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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,016

02/26/2004

Tomoaki Hoshino

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06/29/2006

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP  
1250 CONNECTICUT AVENUE, NW  
SUITE 700  
WASHINGTON, DC 20036

EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/786,016	Applicant(s) TOMOAKI HOSHINO	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/26/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 10/257,965.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/26/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED OFFICE ACTION**

Applicant's preliminary amendment filed on 26 February 2004 is acknowledged and entered. Following the amendment, the original claims 1-23 and 25-31 are canceled.

Currently, claim 24 is pending, and under consideration.

#### **Formal Matters:**

##### ***Information Disclosure Statement***

Applicant's IDS submitted on 2/26/2004 is acknowledged and has been considered. A signed copy is attached hereto.

##### ***Priority acknowledgement***

This application claims benefit of U.S. application No. 10/257,965, which is acknowledged.

##### ***Drawings***

This application lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

Appropriate correction is required.

#### **Rejections under 35 U.S.C. §101:**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 24 is rejected under 35 U.S.C. 101 because the claimed invention reads on non-statutory subject matter. The claim is drawn to "a composition *comprising* ... an IL-18 inhibitor and/or an IL-2 inhibitor", which encompasses a product of nature as some of said inhibitors are naturally occurring in vivo, and thus, is unpatentable to applicant. For example, the IL-18

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binding protein (IL-18BP), which is constitutively expressed in the spleen, and isolated from human urine, is capable of specifically binding IL-18 and neutralizing its biological activity (Novel et al., Immunity, 1999, 10:127-136, especially the "Summary", and page 127, right column, the second paragraph from the last one). It is suggested that applicant use the language "isolated" or "purified" in connection with the inhibitor to indicate the hand of the inventor. See MPEP 2105.

**Rejections Over Prior Art:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi et al. (J. Immuno. Meth., 1997, 206:107-113, provided by applicants).

Taniguchi discloses a hybridoma, clone #125-2H, which produces an anti-human IL-18 monoclonal antibody capable of binding IL-18 and inhibiting the biological activity of IL-18 (Table 1). Additionally, Taniguchi teaches that the mAb exists in the hybridoma culture supernatants, and was purified from such supernatants (page 108, the right column, 2.3, and page 109, the left column, 2.4). Thus, the reference anticipates the present claim 24 as Taniguchi's #125-2H hybridoma culture supernatant (media) containing the mAb is a type of composition, and mAb #125-2H is shown to be an IL-18 inhibitor.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by Gillis (US4,411,993).

Gillis discloses hybridoma cells producing anti-IL-2 monoclonal antibody (4E12 or 4E12B2D10) capable of inhibiting IL-2 activity (the abstract, column 1, lines 7-10, column 3, lines 19-47, and Figure 1). Gillis also teaches that the mAb exists in the culture medium conditioned by hybridoma cells (hybridoma supernatants), and was purified from such medium (the abstract, column 5, lines 58-61, and column 7, lines 16-17). Thus, the reference anticipates

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the present claim 24 as Gillis's 4E12 or 4E12B2D10 hybridoma supernatant containing the mAb is a type of composition, and mAb 4E12 or 4E12B2D10 is shown to be an IL-2 inhibitor.

**Conclusion:**

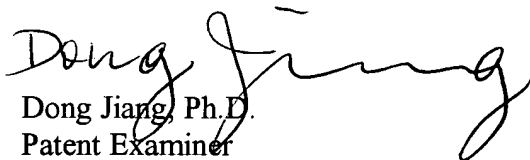
No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in cursive script that reads "Dong Jiang".

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
6/18/06